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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,392	11/22/2006	Kun Yu	4739-P04018US00	9152

110 7590 11/19/2009

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
11/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,392	YU ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,11,12,14,16,18-20,22,23,25-27 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-7, 11, 12, 14, 16, 18-20, 22, 23, 25-27, and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/5/09 has been entered.

Claims 1, 5-7, 11, 12, 14, 16, 18-20, 22, 23, 25-27, and 38 are pending.

Claims 1, 12, 16, 22, and 23 have been amended.

Claims 1, 5-7, 11, 12, 14, 16, 18-20, 22, 23, 25-27, and 38 are currently under consideration.

The Office Action contains New Rejections.

Objections Withdrawn

The objection to claim 1 is withdrawn.

Rejections Withdrawn

The rejection of claims 12 under 35 U.S.C. 102(b) is withdrawn.

The rejection of claims 12 under 35 U.S.C. 103(a) is withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 18-20, 22, 23, 25-27 and 38 remains rejected under 35 U.S.C. 102(b) as being anticipated by Sorlie et al (PNAS, September 2001, 98(19):10869-10874) for the reasons stated in the Office Action of 6/11/09 and for the reasons set-forth below.

Claim 16 is drawn to a kit comprising a plurality of nucleic acid binding members which specifically bind to nucleic acid expression products of genes consisting of SEQ ID NOs:1-13 and a detection reagent, and wherein said kit optionally comprises less than 500 binding members. It is noted that claim 16 does not require the kit comprise more than one binding member that specifically binds to SEQ ID NOs:1-13. Rather, a kit comprising a single binding member that binds any of SEQ ID NO:1-13 in combination with any other binding members is a kit comprising a plurality of nucleic acid binding members which specifically bind to nucleic acid expression products of genes consisting of SEQ ID NOs:1-13. Claim 18 is drawn to the kit of claim 16, further comprising a data analysis tool, wherein the data analysis tool is a computer program. Claim 19 is drawn to the kit of claim 18 wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses. Claim 20 is drawn to the kit of claim 16, comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles

characteristic of a particular prognosis. Claim 22 is drawn to a kit comprising nucleic acid binding members which specifically bind to nucleic acid expression products of genes from a group consisting of SEQ ID NOs:1-13, and wherein said binding members are nucleotide primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR. It is noted that claim 22 does not require the kit comprise more than one binding member that specifically binds to SEQ ID NOs:1-13. Rather, a kit comprising a single binding member that binds any of SEQ ID NO:1-13 in combination with any other binding members is a kit comprising nucleic acid binding members which specifically bind to nucleic acid expression products of genes from a group consisting of SEQ ID NOs:1-13. Claim 23 is drawn to a method comprising isolated nucleic acid expression products from a breast tumor sample comprising SEQ ID NOs:1-13, identifying the expression levels of a prognostic set of genes wherein the prognostic set of genes consists of SEQ ID NO:1-13, and producing from the expression levels an expression profile for said breast tumour sample. It is noted that claim 23 does not require identifying expression levels of every nucleic acid represented by SEQ ID NOs:1-13; rather, the method requires "identifying expression levels of a" prognostic set of genes consisting of SEQ ID NOs:1-13. Methods of identifying expression levels of MDM4, for example, are methods of "identifying expression levels of a" prognostic set of genes consisting of SEQ ID NOs:1-13. Claim 25 is drawn to the method of claim 23 comprising adding the expression profile to a gene expression profile databases. Claim 26 is drawn to the method of claim 23 further comprising comparing the expression

profile with a second expression profile or a plurality of second expression profiles characteristic of a particular prognosis. Claim 27 is drawn to the method of claim 26, comprising the steps (a) isolating nucleic acid expression products from a first breast tumour sample, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of a prognostic set of genes, and creating a first expression profile from the expression levels of the prognostic set of genes in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of genes of step (a), so as to create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles. Claim 38 is drawn to the method of claim 27, wherein the known prognosis and known NPI status comprises a known NPI value.

Sorlie et al teaches a kit comprising a plurality of nucleic acid binding members which specifically bind to nucleic acid expression products of genes consisting of SEQ ID NOs:1-13 (including binding members that specifically bind MCM4 minichromosome maintenance deficient 4) and a detection reagent, wherein said kit optionally comprises less than 500 binding members, and wherein said kit further comprises a data analysis tool, wherein the data analysis tool is a computer program, wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses, and wherein said binding members are nucleotide

primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR (see "Supporting Information" of Microarray Analysis and pages 10869-10870, in particular). Sorlie et al further teaches said kit further comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles characteristic of a particular prognosis (see page 10870, in particular). Sorlie et al further teaches a method comprising isolated nucleic acid expression products from a breast tumor sample, identifying the expression levels of a prognostic set of genes wherein the prognostic set of genes can comprise SEQ ID NO:1-13 (MCM4 minichromosome maintenance deficient 4), and producing from the expression levels an expression profile for said breast tumour sample (Figure 1, in particular). Sorlie et al further teaches said method further comprising adding the expression profile to a gene expression profile databases and further comprising comparing the expression profile with a second expression profile or a plurality of second expression profiles characteristic of a particular prognosis (page 10870 and Figure 3, in particular). Sorlie et al further teaches said method comprising the steps (a) isolating nucleic acid expression products from a first breast tumour sample inherently comprising SEQ ID NO:1-13, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of a prognostic set, and creating a first expression profile from the expression levels of the prognostic set in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said

expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of step (a), so as to create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles (page 10870 and Figure 3, in particular). It is noted that the "known" prognosis, NPI status, and NPI values are inherent properties of a breast tumor sample.

In the Reply of 10/5/09, Applicant argues that Sorlie et al does not disclose a kit with the specific prognostic set of genes recited in the amended claims. Applicant further argues that Sorlie et al does not disclose a method of producing an expression profile with the specific prognostic set of genes recited in the amended claims.

The amendments to the claims and the arguments found in the Reply of 10/5/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that Sorlie et al does not disclose a kit with the specific prognostic set of genes recited in the amended claims, Applicant is arguing limitations not recited in the claims. The claims are not drawn to kits comprising prognostic sets of genes. Rather, the claims are drawn to kits comprising binding members.

In regards to the argument that Sorlie et al does not disclose a method of producing an expression profile with the specific prognostic set of genes recited in the amended claims, Sorlie et al teaches a method comprising producing from expression levels of a prognostic set of genes wherein the prognostic set of genes consists of SEQ ID NO:1-13 an expression profile for a breast tumor sample (page 10870 and Figure 3, in particular). The method comprising producing from expression levels of MCM4 an

expression profile for a breast tumor sample taught by Sorlie et al is a method comprising producing from expression levels of a prognostic set of genes wherein the prognostic set of genes consists of SEQ ID NO:1-13 an expression profile for a breast tumor sample.

Note: In order to expedite prosecution, it is noted the following suggested amendment to claim 23 would remove claims 23, 25-27, and 38 from this rejection:

23. A method of producing a nucleic acid expression profile for a breast tumour sample comprising the steps of

(a) isolating nucleic acid expression products from said breast tumour sample, said sample comprising SEQ ID NOS: 1-13;

(b) ~~identifying expression levels of a prognostic set of genes, wherein the prognostic set of genes consists~~ **detecting the expression levels** of adenine phosphoribosyltransferase (SEQ ID NO:1), MCM4 minichromosome maintenance deficient 4 (S. cerevisiae) (SEQ ID NOS:2-5), exonuclease 1 (SEQ ID NOS:6-12), Metallothionein 1H-like protein (SEQ ID NO:12), and clone IMAGE: 5270727 (SEQ ID NO:13); and

(c) producing from the expression levels an expression profile for said breast tumour sample.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-7,11, 16, 18-20, 22, 23, 25-27, and 38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sorlie et al (PNAS, September 2001, 98(19):10869-10874) as applied to claims 16, 18-20, 22, 23, 25-27, and 38 above, and further in view of Sauerbrei et al (Breast Cancer Research and Treatment, 1997, 42: 149-163) for the reasons stated in the Office Action of 6/11/09 and for the reasons set-forth below.

Claim 1 is drawn to a method comprising obtaining an expression profile of nucleic acid products of a prognostic set of genes from a patient breast tumor sample comprising SEQ ID NO:1-13, comparing the expression profile with a previously determined standard expression signature profile which is of known prognoses, wherein the prognostic set of genes comprises SEQ ID NOs:1-13 and assigning the breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6). It is noted that claim 1 does not require the obtained expression profile of nucleic acid products to include any nucleic acids represented by SEQ ID NOs:1-13; rather, the obtained expression profile of nucleic acid products can be any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 5 is drawn to the method of claim 1 comprising the steps of (a) obtaining a breast tumor sample from the patient and (b) measuring the levels of said nucleic acid expression products in the sample. Claim 6 is drawn to the method of claim 5 wherein step (b)

comprises contacting said nucleic acid expression products obtained from the sample with a plurality of binding members capable of binding to said nucleic acid expression products, wherein such binding is measured. Claim 7 is drawn to the method of claim 6 wherein the binding members are complementary nucleic acid sequences. Claim 11 is drawn to the method of claim 1 further comprising comparing the expression profiles of the prognostic set of genes in the breast tumour sample before and after treatment. Claim 16 is drawn to a kit comprising a plurality of nucleic acid binding members which specifically bind to nucleic acid expression products of genes consisting of SEQ ID NOs:1-13 and a detection reagent, and wherein said kit optionally comprises less than 500 binding members. It is noted that claim 16 does not require the kit comprise more than one binding member that specifically binds to SEQ ID NOs:1-13. Rather, a kit comprising a single binding member that binds any of SEQ ID NO:1-13 in combination with any other binding members is a kit comprising a plurality of nucleic acid binding members which specifically bind to nucleic acid expression products of genes consisting of SEQ ID NOs:1-13. Claim 18 is drawn to the kit of claim 16, further comprising a data analysis tool, wherein the data analysis tool is a computer program. Claim 19 is drawn to the kit of claim 18 wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses. Claim 20 is drawn to the kit of claim 16, comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles characteristic of a particular prognosis. Claim 22 is drawn to a kit comprising nucleic acid binding members which specifically bind to nucleic acid expression products of genes from a group consisting of

SEQ ID NOs:1-13, and wherein said binding members are nucleotide primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR. It is noted that claim 22 does not require the kit comprise more than one binding member that specifically binds to SEQ ID NOs:1-13. Rather, a kit comprising a single binding member that binds any of SEQ ID NO:1-13 in combination with any other binding members is a kit comprising nucleic acid binding members which specifically bind to nucleic acid expression products of genes from a group consisting of SEQ ID NOs:1-13. Claim 23 is drawn to a method comprising isolated nucleic acid expression products from a breast tumor sample comprising SEQ ID NOs:1-13, identifying the expression levels of a prognostic set of genes wherein the prognostic set of genes consists of SEQ ID NO:1-13, and producing from the expression levels an expression profile for said breast tumour sample. It is noted that claim 23 does not require identifying expression levels of every nucleic acid represented by SEQ ID NOs:1-13; rather, the method requires "identifying expression levels of a" prognostic set of genes consisting of SEQ ID NOs:1-13. Methods of identifying expression levels of MDM4, for example, are methods of "identifying expression levels of a" prognostic set of genes consisting of SEQ ID NOs:1-13. Claim 25 is drawn to the method of claim 23 comprising adding the expression profile to a gene expression profile databases. Claim 26 is drawn to the method of claim 23 further comprising comparing the expression profile with a second expression profile or a plurality of second expression profiles characteristic of a particular prognosis. Claim 27 is drawn to the method of claim 26, comprising the steps

(a) isolating nucleic acid expression products from a first breast tumour sample, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of a prognostic set of genes, and creating a first expression profile from the expression levels of the prognostic set of genes in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of genes of step (a), so as to create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles. Claim 38 is drawn to the method of claim 27, wherein the known prognosis and known NPI status comprises a known NPI value.

Sorlie et al teaches a kit comprising a plurality of nucleic acid binding members which specifically bind to nucleic acid expression products of genes consisting of SEQ ID NOs:1-13 (including binding members that specifically bind MCM4 minichromosome maintenance deficient 4) and a detection reagent, wherein said kit optionally comprises less than 500 binding members, and wherein said kit further comprises a data analysis tool, wherein the data analysis tool is a computer program, wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses, and wherein said binding members are nucleotide primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR

(see "Supporting Information" of Microarray Analysis and pages 10869-10870, in particular). Sorlie et al further teaches said kit further comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles characteristic of a particular prognosis (see page 10870, in particular). Sorlie et al further teaches a method comprising isolated nucleic acid expression products from a breast tumor sample, identifying the expression levels of a prognostic set of genes wherein the prognostic set of genes can comprise SEQ ID NO:1-13 (MCM4 minichromosome maintenance deficient 4), and producing from the expression levels an expression profile for said breast tumour sample (Figure 1, in particular). Sorlie et al further teaches said method further comprising adding the expression profile to a gene expression profile databases and further comprising comparing the expression profile with a second expression profile or a plurality of second expression profiles characteristic of a particular prognosis (page 10870 and Figure 3, in particular). Sorlie et al further teaches said method comprising the steps (a) isolating nucleic acid expression products from a first breast tumour sample inherently comprising SEQ ID NO:1-13, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of a prognostic set, and creating a first expression profile from the expression levels of the prognostic set in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of step (a), so as to

create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles (page 10870 and Figure 3, in particular). It is noted that the "known" prognosis, NPI status, and NPI values are inherent properties of a breast tumor sample.

Sorlie et al does not specifically teach a method comprising assigning the breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6). However, this deficiency is made up in the teachings of Sauerbrei et al.

Sauerbrei et al teaches a method of determining a prognosis for a patient with breast cancer comprising assigning a breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6) (see left column of page 151, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to determine a prognosis for a patient with breast cancer by performing the method of Sorlie et al and assigning breast tumor samples of said method as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6) using the method of Sauerbrei et al because combining two methods of determining a prognosis for breast cancer would be more accurate than performing either method alone. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for determining a prognosis for a patient with breast cancer by performing the method of Sorlie et al and assigning breast tumor samples of said method as being of either high

NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6) using the method of Sauerbrei et al because Sauerbrei et al teaches a method of determining a prognosis for a patient with breast cancer comprising assigning a breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6) (see left column of page 151, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

In the Reply of 10/5/09, Applicant argues neither Sorlie nor Saubrei disclose or suggest a correlation between NPI status and upregulation and downregulation of the prognostic set of genes encompassed by the claims.

The amendments to the claims and the arguments found in the Reply of 10/5/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that neither Sorlie nor Saubrei disclose or suggest a correlation between NPI status and upregulation and downregulation of the prognostic set of genes encompassed by the claims, correlations between NPI status and upregulation and downregulation of the genes recited in the claims are inherent correlations.

New Rejections Necessitated by Amendments

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (PNAS, 1994, 91: 9257-9261) in view of Jin R et al (Carcinogenesis, January 2002, 23(1):81-86) and Sorlie et al (PNAS, September 2001, 98(19):10869-10874).

Claim 14 is drawn to an apparatus comprising a solid support to which are attached a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one of a prognostic set of genes, wherein the prognostic set includes SEQ ID NOs:1-13, and wherein said solid support houses nucleic acid binding members for not more than 500 different genes and the solid support has attached thereto only binding members which are capable of specifically and independently binding to expression products of the nucleic acids encoded by SEQ ID NOs:1-309. It is noted that claim 14 does not require the binding members to bind SEQ ID NOs:1-13; rather, claim 14 encompasses apparatuses comprising a solid support and binding member wherein the binding members consist of any two binding members that specifically and independently binding to expression products of the nucleic acids encoded by SEQ ID NOs:1-309.

Jensen et al teaches a method of detecting early stages of breast cancer using a binding member that specifically and independently bind to expression products of SEQ ID NOS:171-178 (Ribonucleotide reductase M2 polypeptide) (see Abstract and pages 9259-9260, in particular).

Jensen et al does not specifically teach an apparatus comprising a solid support to which the binding member of Jensen et al is attached or wherein said apparatus comprises other binding members that specifically and independently binding to expression products of the nucleic acids encoded by SEQ ID NOs:1-309. However, these deficiencies are made up in the teachings of Jin R et al and Sorlie et al.

Jin R et al teaches a method of identifying proliferative high-grade breast cancer using a binding member that specifically and independently bind to expression products of SEQ ID NOS:113-117 (Metallothionein 2A) (see Abstract, in particular).

Sorlie et al teaches methods of characterizing breast cancer using apparatuses with attached binding members which specifically and independently bind to expression products (see above).

One of ordinary skill in the art at the time the invention was made would have been motivated to attach the binding members of Jensen et al and Jin R et al to a solid support as done by Sorlie et al in order to characterize patients suspected of having breast cancer because Jensen et al teaches a method of detecting early stages of breast cancer using a binding member that specifically and independently bind to expression products of SEQ ID NOS:171-178 (Ribonucleotide reductase M2 polypeptide) (see Abstract and pages 9259-9260, in particular), Jin R et al teaches a method of identifying proliferative high-grade breast cancer using a binding member that specifically and independently bind to expression products of SEQ ID NOS:113-117 (Metallothionein 2A) (see Abstract, in particular), and Sorlie et al teaches methods of characterizing breast cancer using apparatuses with attached binding members which specifically and independently bind to expression products (see above). Further, the instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same

purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Appling the same logic to the instant claims, given the teachings of the prior art, it would have been obvious to combine the binding member of Jensen et al and Jin R et al with the apparatus of Sorlie et al because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as distinguishing between breast tumor subclasses. Further, one of ordinary skill in the art would have reasonably expected to characterize subjects suspected of having breast cancer upon using the combination of the binding member of Jensen et al and Jin R et al attached to the apparatus of Sorlie since both had been demonstrated in the prior art to be reasonably predictive of characterizing subjects suspected of having breast cancer. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorlie et al (PNAS, September 2001, 98(19):10869-10874) in view of Dai et al (US 7,171,311 B2; 1/30/07).

Claim 12 is drawn to an apparatus comprising a solid support to which are attached a plurality of nucleic acid binding members, each binding member specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes consists of SEQ ID NOS:1-13. It is noted that an apparatus comprising more than one nucleic acid binding member that specifically and

independently binds to any of SEQ ID NOs:1-13 is an apparatus a plurality of nucleic acid binding members, each binding member specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes consists of SEQ ID NOS:1-13.

Sorlie et al teaches an apparatus used for distinguishing breast tumor subclasses comprising a solid support to which is attached a nucleic acid binding member that specifically and independently binds to MCM4 minichromosome maintenance deficient 4 (SEQ ID NOS:2-5) (see "Supporting Information" of Microarray Analysis and pages 10869-10870, in particular).

Sorlie does not specifically teach nucleic acid binding members that specifically and independently bind to SEQ ID NOS: 1 or 6-13 on the solid support. However, this deficiency is made up in the teachings of Dai et al.

Dai et al teaches SEQ ID NO:944, which is 100% identical to instant SEQ ID NO:1 (see sequence comparison below). Dai et al further teaches an apparatus used for distinguishing breast tumor subclasses comprising a solid support to which is attached a nucleic acid binding member that specifically and independently binds to SEQ ID NO:944 (see columns 32 and 131, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to include the binding member of Dai et al on the solid support of Sorlie et al when performing the method of Sorlie et al because Sorlie et al teaches the apparatus of Sorlie et al is to distinguish between breast tumor subclasses and the binding member of Dai et al distinguishes between breast tumor subclasses. One of

ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for including the binding member of Dai et al on the solid support of Sorlie et al when performing the method of Sorlie et al because Sorlie et al teaches the apparatus of Sorlie et al is to distinguish between breast tumor subclasses and the binding member of Dai et al distinguishes between breast tumor subclasses. Further, the instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Appling the same logic to the instant claims, given the teachings of the prior art, it would have been obvious to combine the binding member of Dai et al with the apparatus of Sorlie et al because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as distinguishing between breast tumor subclasses. Further, one of ordinary skill in the art would have reasonably expected to distinguish between breast tumor subclasses upon the combination of the binding member of Dai et al with the apparatus of Sorlie since both had been demonstrated in the prior art to be reasonably predictive of distinguishing breast tumor subclasses. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Comparison of instant SEQ ID NO:1 and SEQ ID NO:944:

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  Query Match             100.0%;  Score 2921;  DB 5;  Length 2921;
  Best Local Similarity   100.0%;  Pred. No. 0;
  Matches 2921;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 GCACGAGGTGCCACATGCGATCTCTGAGATATGTACACAGTCATTCTTACTATCGCACTC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 GCACGAGGTGCCACATGCGATCTCTGAGATATGTACACAGTCATTCTTACTATCGCACTC 60

Qy         61 AGCCATTCTTACTACGCTAAAGAAGAAATAATTATTCGAGGATATTTGCCTGGCCCAGAA
120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 AGCCATTCTTACTACGCTAAAGAAGAAATAATTATTCGAGGATATTTGCCTGGCCCAGAA
120

Qy        121 GAAACTTATGTAAATTTCATGAACTATTATATCCGTTTTCCTCGGAGTGAGAGAAAACTC
180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 GAAACTTATGTAAATTTCATGAACTATTATATCCGTTTTCCTCGGAGTGAGAGAAAACTC
180

Qy        181 TTTTTAGATATCATCTGAGAGGTAGTTAATTTGGCACCATGGGGATACAGGGATTGCTAC
240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 TTTTTAGATATCATCTGAGAGGTAGTTAATTTGGCACCATGGGGATACAGGGATTGCTAC
240

Qy        241 AATTTATCAAAGAAGCTTCAGAACCCATCCATGTGAGGAAGTATAAAGGGCAGGTAGTAG
300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 AATTTATCAAAGAAGCTTCAGAACCCATCCATGTGAGGAAGTATAAAGGGCAGGTAGTAG
300

Qy        301 CTGTGGATACATATTGCTGGCTTCACAAAGGAGCTATTGCTTGTGCTGAAAAACTAGCCA
360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 CTGTGGATACATATTGCTGGCTTCACAAAGGAGCTATTGCTTGTGCTGAAAAACTAGCCA
360

Qy        361 AAGGTGAACCTACTGATAGGTATGTAGGATTTTGTATGAAATTTGTAAATATGTTACTAT
420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 AAGGTGAACCTACTGATAGGTATGTAGGATTTTGTATGAAATTTGTAAATATGTTACTAT
420

Qy        421 CTCATGGGATCAAGCCTATTCTCGTATTTGATGGATGTACTTTACCTTCTAAAAAGGAAG
480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 CTCATGGGATCAAGCCTATTCTCGTATTTGATGGATGTACTTTACCTTCTAAAAAGGAAG
480
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Qy        481 TAGAGAGATCTAGAAGAGAAAGACGACAAGCCAATCTTCTTAAGGGAAAGCAACTTCTTC
540

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Db        481 TAGAGAGATCTAGAAGAGAAAGACGACAAGCCAATCTTCTTAAGGGAAAGCAACTTCTTC
540

Qy        541 GTGAGGGGAAAGTCTCGGAAGCTCGAGAGTGTTTCACCCGGTCTATCAATATCACACATG
600

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Db        541 GTGAGGGGAAAGTCTCGGAAGCTCGAGAGTGTTTCACCCGGTCTATCAATATCACACATG
600

Qy        601 CCATGGCCCACAAAGTAATTAAAGCTGCCCGGTCTCAGGGGGTAGATTGCCTCGTGGCTC
660

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Db        601 CCATGGCCCACAAAGTAATTAAAGCTGCCCGGTCTCAGGGGGTAGATTGCCTCGTGGCTC
660

Qy        661 CCTATGAAGCTGATGCGCAGTTGGCCTATCTTAACAAAGCGGGAATTGTGCAAGCCATAA
720

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Db        661 CCTATGAAGCTGATGCGCAGTTGGCCTATCTTAACAAAGCGGGAATTGTGCAAGCCATAA
720

Qy        721 TTACAGAGGACTCGGATCTCCTAGCTTTTGGCTGTAAAAAGGTAATTTTAAAGATGGACC
780

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Db        721 TTACAGAGGACTCGGATCTCCTAGCTTTTGGCTGTAAAAAGGTAATTTTAAAGATGGACC
780

Qy        781 AGTTTGGAAATGGACTTGAAATTGATCAAGCTCGGCTAGGAATGTGCAGACAGCTTGGGG
840

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Db        781 AGTTTGGAAATGGACTTGAAATTGATCAAGCTCGGCTAGGAATGTGCAGACAGCTTGGGG
840

Qy        841 ATGTATTCACGGAAGAGAAGTTTCGTTACATGTGTATTCTTTCAGGTTGTGACTACCTGT
900

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Db        841 ATGTATTCACGGAAGAGAAGTTTCGTTACATGTGTATTCTTTCAGGTTGTGACTACCTGT
900

Qy        901 CATCACTGCGTGGGATTGGATTAGCAAAGGCATGCAAAGTCCTAAGACTAGCCAATAATC
960

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Db        901 CATCACTGCGTGGGATTGGATTAGCAAAGGCATGCAAAGTCCTAAGACTAGCCAATAATC
960

Qy        961 CAGATATAGTAAAGGTTATCAAGAAAATTGGACATTATCTCAAGATGAATATCACGGTAC
1020

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Db        961 CAGATATAGTAAAGGTTATCAAGAAAATTGGACATTATCTCAAGATGAATATCACGGTAC
1020
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Qy       1021 CAGAGGATTACATCAACGGGTTTATTCGGGCCAACAATACCTTCCTCTATCAGCTAGTTT
1080

Db       1021 CAGAGGATTACATCAACGGGTTTATTCGGGCCAACAATACCTTCCTCTATCAGCTAGTTT
1080

Qy       1081 TTGATCCCATCAAAAGGAAACTTATTCCTCTGAACGCCTATGAAGATGATGTTGATCCTG
1140

Db       1081 TTGATCCCATCAAAAGGAAACTTATTCCTCTGAACGCCTATGAAGATGATGTTGATCCTG
1140

Qy       1141 AAACACTAAGCTACGCTGGGCAATATGTTGATGATTCCATAGCTCTTCAAATAGCACTTG
1200

Db       1141 AAACACTAAGCTACGCTGGGCAATATGTTGATGATTCCATAGCTCTTCAAATAGCACTTG
1200

Qy       1201 GAAATAAAGATATAAATACTTTTGAACAGATCGATGACTACAATCCAGACACTGCTATGC
1260

Db       1201 GAAATAAAGATATAAATACTTTTGAACAGATCGATGACTACAATCCAGACACTGCTATGC
1260

Qy       1261 CTGCCCATTCAAGAAGTCGTAGTTGGGATGACAAAACATGTCAAAAGTCAGCTAATGTTA
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Db       1261 CTGCCCATTCAAGAAGTCGTAGTTGGGATGACAAAACATGTCAAAAGTCAGCTAATGTTA
1320

Qy       1321 GCAGCATTTGGCATAGGAATTACTCTCCCAGACCAGAGTCGGGTACTGTTTCAGATGCCC
1380

Db       1321 GCAGCATTTGGCATAGGAATTACTCTCCCAGACCAGAGTCGGGTACTGTTTCAGATGCCC
1380

Qy       1381 CACAATTGAAGGAAAATCCAAGTACTGTGGGAGTGGAACGAGTGATTAGTACTAAAGGGT
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Db       1381 CACAATTGAAGGAAAATCCAAGTACTGTGGGAGTGGAACGAGTGATTAGTACTAAAGGGT
1440

Qy       1441 TAAATCTCCCAAGGAAATCATCCATTGTGAAAAGACCAAGAAGTGCAGAGCTGTCAGAAG
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Db       1441 TAAATCTCCCAAGGAAATCATCCATTGTGAAAAGACCAAGAAGTGCAGAGCTGTCAGAAG
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Qy       1501 ATGACCTGTTGAGTCAGTATTCTCTTTCATTTACGAAGAAGACCAAGAAAAATAGCTCTG
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Db       1501 ATGACCTGTTGAGTCAGTATTCTCTTTCATTTACGAAGAAGACCAAGAAAAATAGCTCTG
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Qy       1561 AAGGCAATAAATCATTGAGCTTTTCTGAAGTGTTTGTGCCTGACCTGGTAAATGGACCTA
1620

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Db       1561 AAGGCAATAAATCATTGAGCTTTTCTGAAGTGTTTGTGCCTGACCTGGTAAATGGACCTA
1620

Qy       1621 CTAACAAAAAGAGTGTAAGCACTCCACCTAGGACGAGAAATAAATTTGCAACATTTTTAC
1680

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Db       1621 CTAACAAAAAGAGTGTAAGCACTCCACCTAGGACGAGAAATAAATTTGCAACATTTTTAC
1680

Qy       1681 AAAGGAAAAATGAAGAAAGTGGTGCAGTTGTGGTTCCAGGGACCAGAAGCAGGTTTTTTT
1740

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Db       1681 AAAGGAAAAATGAAGAAAGTGGTGCAGTTGTGGTTCCAGGGACCAGAAGCAGGTTTTTTT
1740

Qy       1741 GCAGTTCAGATTCTACTGACTGTGTATCAAACAAAGTGAGCATCCAGCCTCTGGATGAAA
1800

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1800

Qy       1801 CTGCTGTCACAGATAAAGAGAACAATCTGCATGAATCAGAGTATGGAGACCAAGAAGGCA
1860

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Db       1801 CTGCTGTCACAGATAAAGAGAACAATCTGCATGAATCAGAGTATGGAGACCAAGAAGGCA
1860

Qy       1861 AGAGACTGGTTGACACAGATGTAGCACGTAATTCAAGTGATGACATTCCGAATAATCATA
1920

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Db       1861 AGAGACTGGTTGACACAGATGTAGCACGTAATTCAAGTGATGACATTCCGAATAATCATA
1920

Qy       1921 TTCCAGGTGATCATATTCCAGACAAGGCAACAGTGTTTACAGATGAAGAGTCCTACTCTT
1980

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Db       1921 TTCCAGGTGATCATATTCCAGACAAGGCAACAGTGTTTACAGATGAAGAGTCCTACTCTT
1980

Qy       1981 TTAAGAGCAGCAAATTTACAAGGACCATTTCACCACCCACTTTGGGAACACTAAGAAGTT
2040

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Db       1981 TTAAGAGCAGCAAATTTACAAGGACCATTTCACCACCCACTTTGGGAACACTAAGAAGTT
2040

Qy       2041 GTTTTAGTTGGTCTGGAGGTCTTGGAGATTTTTCAAGAACGCCGAGCCCCTCTCCAAGCA
2100

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2100
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Qy       2101 CAGCATTGCAGCAGTTCCGAAGAAAGAGCGATTCCCCCACCTCTTTGCCTGAGAATAATA
2160

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2160

Qy       2161 TGTCTGATGTGTCGCAGTTAAAGAGCGAGGAGTCCAGTGACGATGAGTCTCATCCCTTAC
2220

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Db       2161 TGTCTGATGTGTCGCAGTTAAAGAGCGAGGAGTCCAGTGACGATGAGTCTCATCCCTTAC
2220

Qy       2221 GAGAAGGGGCATGTTCTTCACAGTCCCAGGAAAGTGGAGAATTCTCACTGCAGAGTTCAA
2280

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Db       2221 GAGAAGGGGCATGTTCTTCACAGTCCCAGGAAAGTGGAGAATTCTCACTGCAGAGTTCAA
2280

Qy       2281 ATGCATCAAAGCTTTCTCAGTGCTCTAGTAAGGACTCTGATTCAGAGGAATCTGATTGCA
2340

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Db       2281 ATGCATCAAAGCTTTCTCAGTGCTCTAGTAAGGACTCTGATTCAGAGGAATCTGATTGCA
2340

Qy       2341 ATATTAAGTTACTTGACAGTCAAAGTGACCAGACCTCCAAGCTATGTTTATCTCATTTCT
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2460

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Db       2401 CAAAAAAAGACACACCTCTAAGGAACAAGGTTCCTGGGCTATATAAGTCCAGTTCTGCAG
2460

Qy       2461 ACTCTCTTTCTACAACCAAGATCAAACCTCTAGGACCTGCCAGAGCCAGTGGGCTGAGCA
2520

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Db       2461 ACTCTCTTTCTACAACCAAGATCAAACCTCTAGGACCTGCCAGAGCCAGTGGGCTGAGCA
2520

Qy       2521 AGAAGCCGGCAAGCATCCAGAAGAGAAAGCATCATAATGCCGAGAACAAGCCGGGGTTAC
2580

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Qy       2581 AGATCAAACTCAATGAGCTCTGGAAAAACTTTGGATTTAAAAAATTCTGAAAAGCTTCCT
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Qy       2641 CCTTGTAAGAAACCCCTGTCCCCAGTCAGAGATAACATCCAACTAACTCCAGAAGCGGAA
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Db       2641 CCTTGTAAGAAACCCCTGTCCCCAGTCAGAGATAACATCCAACTAACTCCAGAAGCGGAA
2700

Qy       2701 GAGGATATATTTAACAAACCTGAATGTGGCCGTGTTCAAAGAGCAATATTCCAGTAAATG
2760

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2760

Qy       2761 CAGACTGCTGCAAAGCTTTTGCCTGCAAGAGAATCTGATCAATTTGAAGTCCCTGTTTGG
2820

Db       2761 CAGACTGCTGCAAAGCTTTTGCCTGCAAGAGAATCTGATCAATTTGAAGTCCCTGTTTGG
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Qy       2821 GAATGAGGCACTTATCAGCATGAAGAATTTTTTCTCATTCTGTGCCATTTTAAAAATAGA
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Db       2821 GAATGAGGCACTTATCAGCATGAAGAATTTTTTCTCATTCTGTGCCATTTTAAAAATAGA
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Qy       2881 ATACATTTTGTATATTAACTTTAAAAAAAAAAAAAAAAAA 2921

Db       2881 ATACATTTTGTATATTAACTTTAAAAAAAAAAAAAAAAAA 2921
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Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642